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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,398	04/30/2005	Charles C. Hart	2395-USP-PCT-US	9071

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APPLIED MEDICAL RESOURCES CORPORATION
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EXAMINER

NEAL, TIMOTHY J

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/533,398		HART, CHARLES C.	
	Examiner		Art Unit	
	Timothy J. Neal		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 31-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 and 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Invention I Species A in the reply filed on 9/08/2006 is acknowledged. The traversal is on the ground(s) that figures 15A-18 further show Invention I. Also, the Applicant argues that two species is reasonable under 37 CFR 1.141. The Examiner will consider figures 15A-18 to be drawn to Invention I Species A, however this does not change the claims that are drawn to the elected species. The argument that two species is reasonable under 37 CFR 1.141 is not found to be persuasive because the Applicant has not argued that there is a generic claim from which both species depend or that the species are not patentably distinct. Also, the Examiner still considers the two clip appliers to clearly be distinct species.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the handle (Claim 22), the plurality of slots in each of the opposed jaws (Claim 29), and the first slot of one jaw and second slot of the other jaw (Claims 45-47) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 45 through 47 are not fully supported by the specification. Page 15 Lines 10-13 suggest the slots

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disclosed in claims 45 through 47, but there is no description of how the slots operably receive the tissue engaging members.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 30, and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There is no clear explanation of how the plurality of slots are configured in each jaw so that the jaws may simultaneously apply multiple staple-clips. Although Figure 17 shows two staple-clips that have been applied to a vessel, there is no description or drawing that shows how they got there. The first and second slots as disclosed in claims 45-47 are lacking similar descriptions. There is no description of how the tissue engaging member would be secured by a slot in the jaws, and there is no description of where the slot is located on the jaw or what it looks like. The drawings show no evidence of a slot, and therefore, are of no help to the Examiner. The Examiner has concluded that any portion of the jaw that is capable of holding or retaining the medical device or staple-clip will be

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considered a slot. Because of the insufficient description of the plurality of slots disclosed in claim 29, the Examiner has interpreted the claim to encompass any device capable of applying more than one clip without reloading the device.

Claim 30 discloses a cutter member. Page 15 Lines 13-16 describes a cutter member, but there is no description of how it is to be used with the clip applier. Figure 18 shows a cutter, but there is no evidence of its structural relationship to the clip applier. The Examiner cannot determine where the cutter element would be placed on the clip applier or the means for actuating the cutter element. Therefore, the Examiner has determined that a person of ordinary skill would not be able to make or use the device as disclosed. Any portion of the clip applier that is capable of transecting body tissue will be considered a cutting member. There is no limitation on how the structure of the cutting member relates to the clip applier.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-30 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Hart et al. (US 6,139,555).

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Hart discloses:

22. An applier, the applier comprising: an elongate shaft having a proximal end and a distal end (Fig 1 Item 12); a pair of opposed jaws connected at the distal end of the elongate shaft (Fig 1 Item 30); a handle operably connected at the proximal end of the elongate shaft to open and close the opposed jaws (Fig 1 Items 50 and 52); and a sliding member operably connected within the elongate shaft to advance the securing member over the first and the second tissue-engaging members after closure of the jaws (Fig 1 Item 56).

23. The applier of claim 22, wherein the jaws operate to apply the first and the second tissue-engaging members around a target body tissue or vessel (Col 2 Line 52).

24. The applier of claim 23, wherein the first and the second tissue-engaging members are applied to the jaws either manually or automatically (Fig 4).

25. The applier of claim 23, wherein the jaws are compressed using only a force required for a specific surgical procedure such as occlusion, ligation or fixation (Col 2 Line 40).

26. The applier of claim 25, wherein the first and the second tissue-engaging members and the securing member are introduced to a surgical site in an un-

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assembled condition through a small port or trocar (Col 2 Line 22).

27. The applier of claim 26, wherein the sliding member operates to urge the securing member forward and over the first and second tissue-engaging members to secure the medical device (inherent, see Col 3 Line 25).

28. The applier of claim 27, wherein the applier and the medical device are sized and configured for use in a minimally invasive or laparoscopic surgical procedure (Col 2 Line 22).

29. The applier of claim 22, further comprising a plurality of slots in each of the opposed jaws to receive a plurality of the medical devices or multiple staple-clips to simultaneously apply the medical devices or staple-clips (Fig 2 Items 24).

30. The applier of claim 29, further comprising a cutting member to be advanced between the medical devices or staple-clips after they have been applied to transect the body tissue or vessel between the medical devices or staple-clips (Fig 2 Item 40).

44. The applier of claim 22, wherein the elongate shaft is sized to fit through a surgical trocar port (Col 2 Line 22).

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45. The applier of claim 45 wherein one of the jaws has a first slot arranged to operably receive the first tissue engaging member without the securing member and another of the jaws has a second slot arranged to operably receive the second tissue engaging member without the securing member (Fig 2 Item 38).

46. The applier of claim 45 wherein the first slot is arranged to operably receive a first portion of the securing member and the second slot is arranged to operably receive a second portion of the securing member, the first and second portions of the securing member being different (Fig 2 Item 38).

47. The applier of claim 22 wherein one of the jaws has a first slot sized and arranged to simultaneously hold the first tissue engaging member and a first portion of the securing member and another of the jaws has a second slot arranged to simultaneously hold the second tissue engaging member and a second portion of the securing member (Fig 2 Item 38).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

9/15/06